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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Agency for Healthcare Research and Quality

Scientific Information Request Therapies for Clinically Localized
Prostate Cancer

AGENCY: Agency for Healthcare Research and Quality (AHRQ), HHS.

ACTION: Request for Scientific Information Submissions

SUMMARY: The Agency for Healthcare Research and Quality (AHRQ) is seeking scientific information submissions from medical device manufacturers with products falling within the following UMDNS product codes: Brachytherapy Systems [20-352]; Cyclotrons [15-818]; Radiotherapy Systems, Linear Accelerator [12-364]; Radiotherapy Systems, and Proton Beam [20-546]. Scientific information is being solicited to inform the update of our Comparative Effectiveness Review of Therapies for Clinically Localized Prostate Cancer which is currently being conducted by one of the Evidence-based Practice Centers for the AHRQ Effective Health Care Program. Access to published and unpublished pertinent scientific information on this device will improve the quality of this comparative effectiveness review. AHRQ is requesting this scientific information and conducting this comparative effectiveness review pursuant to Section 1013 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Public Law 108-173.

DATES: Submission-Deadline-on or-before [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES:

E-mail submissions: sips@epc-src.org

Print submissions:

Mailing Address: Portland VA Research Foundation, Scientific Resource Center, ATTN: Scientific Information Packet Coordinator, PO Box 69539, Portland, OR 97239

Shipping Address: (FedEx, UPS, etc) Portland VA Research Foundation, Scientific Resource Center, ATTN: Scientific Information Packet Coordinator, 3710 SW US Veterans Hospital Road, Mail Code: R&D 71, Portland, OR 97239

FOR FURTHER INFORMATION CONTACT:

Robin Paynter, Scientific Information Packet Coordinator, Telephone: 503-220-8262 x58652 or Email: sips@epc-src.org.

SUPPLEMENTARY INFORMATION:

In accordance with Section 1013 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Public Law 108-173, the Agency for Healthcare Research and Quality has commissioned one of the Effective Health Care (EHC)

Program Evidence-based Practice Centers to complete a comparative effectiveness review of the evidence for Therapies for Clinically Localized Prostate Cancer: An Update of a 2008 Comparative Effectiveness Review.

The EHC Program is dedicated to identifying as many studies as possible that are relevant to the questions for each of its reviews. In order to do so, we are supplementing the usual manual and electronic database searches of the literature by requesting information (e.g., details of studies conducted) through public information requests, including via the Federal Register and direct postal and/or online solicitations. We are looking for studies that report on Therapies for Clinically Localized Prostate Cancer, including those that describe adverse events, as specified in the key questions detailed below. The entire research protocol, including the key questions, is also available online at: <http://www.effectivehealthcare.AHRQ.gov/search-for-guides-reviews-and-reports/?pageaction=displayproduct&productID=1434#7270>

This notice is a request for information about the following:

- A current product label, if applicable (preferably an electronic PDF file).
- Information identifying published randomized controlled trials and observational studies relevant to the clinical outcomes. AHRQ is interested in receiving both citations and reprints. Information identifying unpublished randomized controlled trials and observational studies relevant to the clinical outcomes. If possible, please provide a summary that includes the following elements: study number, study period, design, methodology, indication and diagnosis, proper use instructions, inclusion and exclusion criteria, primary and secondary outcomes, baseline characteristics, number of patients. screened/eligible/enrolled/lost to withdrawn/follow-up/analyzed, and effectiveness/efficacy and safety results.
- Registered ClinicalTrials.gov studies. Please provide a list including the ClinicalTrials.gov identifier, condition, and intervention.

Your contribution is very beneficial to this-program. This is a-voluntary-request for information, and all costs for complying with this request must be borne by the submitter. You may wish to indicate whether or not the submission comprises all of the complete information available.

Please Note: The contents of all submissions, regardless of format, will be available to the public upon request unless prohibited by law.

The draft of this review will be posted on AHRQ's EHC program website and available for public comment for a period of 4 weeks. If you would like to be notified when the draft is posted, please sign up for the e-mail list at: <http://effectivehealthcare.AHRQ.gov/index.cfm/join-the-email-list1/>.

Scope and Key Questions

This update examines the same four key questions as in the original 2008 report on the comparative effectiveness of treatments for clinically localized prostate cancer. Although these key questions were reviewed and approved by AHRQ and discussed with Technical Expert Panel (TEP) members for the original report, we presented them for discussion with a newly convened TEP for this update and made changes as necessary. This update will summarize the more recent evidence comparing the relative effectiveness and safety of treatment options for

clinically localized prostate cancer. The key questions we will address are as follows:

Key Question 1

What are the comparative risks and benefits of the following therapies for clinically localized prostate cancer?

- a. Radical prostatectomy, including open (retropubic and perineal) and laparoscopic (with or without robotic assistance) approaches
- b. External Beam Radiotherapy, including standard therapy and therapies designed to decrease exposure to normal tissues such as 3D conformal radiation therapy, intensity-modulated radiation therapy, proton beam therapy, and stereotactic body radiation therapy
- c. Interstitial brachytherapy
- d. Cryosurgery
- e. Watchful waiting
- f. Active surveillance
- g. Hormonal therapy as primary therapy, adjuvant, or neoadjuvant to other therapies
- h. High-intensity focused ultrasound

Key Question 2

How do specific patient characteristics (e.g., age, race/ethnicity, presence or absence of comorbid illness, preferences such as trade-off of treatment-related adverse effects vs. potential for disease progression) affect the outcomes of these therapies overall and differentially?

Key Question 3

How do provider/hospital characteristics affect outcomes of these therapies overall and differentially (e.g., geographic region, case volume, learning curve)?

Key Question 4

How do tumor characteristics (e.g., Gleason score, tumor volume, screen-detected vs. clinically detected tumors, and PSA levels) affect the outcomes of these therapies overall and differentially?

Population, Interventions, Comparators, Outcomes, Timing, Settings Criteria
Population

· Key Questions 1, 2, 3, and 4: Men considered to have clinically localized prostate cancer (T1 to T2, N0 to X, M0 to X) regardless of age, histologic grade, or PSA level. Articles will be excluded if men with disease stage higher than T2 were enrolled and outcomes were not stratified by stage.

Interventions

- For Key Questions 1, 2, 3, and 4, we will include treatment options for men with clinically localized prostate cancer: radical prostatectomy (including retropubic, perineal, laparoscopic, robotic-assisted), watchful waiting, active surveillance, External Beam Radiotherapy (including conventional radiation, Intensity Modulated Radiotherapy, 3D conformal radiation, proton beam, and stereotactic body radiation therapy), brachytherapy, androgen deprivation therapy, high-intensity focused ultrasound, and cryotherapy.

Comparators

- Any of the interventions of interest above or watchful waiting.

Outcomes

- The primary outcome is overall mortality or survival. Additional outcomes include prostate-cancer-specific mortality or survival, biochemical (PSA) progression, metastatic and/or clinical progression-free survival, health status, and quality of life. We will focus primarily on common and severe adverse events of treatment including bowel, bladder, and sexual dysfunction, as well as harms from biopsy such as bleeding and nosocomial infections.

- For Key Question 3, we plan to examine outcomes after radical prostatectomy, the most common treatment for localized prostate cancer, in association with provider location, case volume, and affiliation with academic centers.

Timing

- Duration of follow-up will be appropriate for the outcome under consideration.

Settings

- No restrictions by setting.

Dated: April 15, 2013

Carolyn M. Clancy,
AHRQ, Director